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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,634	12/17/2001	Kimberly A. Szytk	21402-221 (Cura 521)	4413

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,634

Applicant(s)

SHIMKETS ET AL.

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 42-51 are pending in the application.
- [2] Applicants' amendment to the claims, filed October 29, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] In a transmittal letter filed October 29, 2004, there is a listing for a supplemental information disclosure statement. Also, applicants indicate the IDS submitted October 22, 2003 has been corrected and request the examiner to consider the references cited in the corrected IDS, submitted with the instant response. However, the examiner can find no Form PTO-1449 in the papers filed October 29, 2004.
- [4] Applicants' arguments filed October 29, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Information Disclosure Statement

- [6] As stated in a previous Office action, the information disclosure statement filed October 22, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the cited U.S. patent application publications are not identified by applicant and publication date as required by 37 CFR 1.98 (b)(2). It has been placed in

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the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification/Informalities

[7] The objection to the specification for the improper citation of trademarks is maintained for the reasons of record as set forth at item [11] of the Office action mailed April 29, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants assert trademarks have been properly used and identified in the specification. However, as stated in a previous Office action, the trademarks cited in the specification should be capitalized wherever they appear and be accompanied by the generic terminology.

Claim Rejections - 35 USC §§ 101 and 112, First Paragraph

[8] The utility rejection of claims 42-51 under 35 U.S.C. 101 and the corresponding enablement rejection of claims 42-51 under 35 U.S.C. 112, first paragraph, are maintained for the reasons of record as stated in items [12] and [13] of the Office action mailed April 29, 2004 and for the reasons stated below.

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RESPONSE TO ARGUMENT: Applicants point to the specification's disclosure that the claimed nucleic acid can be used in diagnosis as an assertion of a specific and substantial utility for the claimed invention. Applicants argue the specification demonstrates decreased expression of the claimed nucleic acid in normal brain temporal cortex tissue as compared to that of patients diagnosed with Alzheimer's disease and that based on this evidence, a skilled artisan would know to detect and compare the expression of SEQ ID NO:11 in samples of temporal cortex tissues to differentiate diseased tissues from normal tissues. Applicants' argument is not found persuasive.

The examiner maintains the position that the specification fails to assert a specific and substantial utility for the claimed invention. Here, applicants assert the utility for the claimed invention is for the diagnosis of Alzheimer's disease. However, there is no evidence provided in the specification that one can use the claimed nucleic acid for such use. It is noted that, while some of the control and diseased samples exhibit differential expression, there is no indication that differential expression of SEQ ID NO:11 can be used as a diagnostic marker of Alzheimer's disease or any other disease or disorder. In this case, it is just as likely that the differential expression is due to some other unidentified disease state that may or may not be associated with Alzheimer's disease. Also, it is noted that the expression level of SEQ ID NO:11 in at least one of the diseased tissue samples was lower than at least one of the normal samples and the expression level of SEQ ID NO:11 in at least one of the normal samples is statistically equivalent to at least one of the diseased tissue samples. At

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least for these reasons, it is the examiner's position that further experimentation is required for a skilled artisan to determine whether SEQ ID NO:11 can be used to diagnose Alzheimer's disease. Therefore, the asserted utility for the claimed invention, *i.e.*, the use of the claimed nucleic acid for disease diagnosis, is not substantial.

Regarding claim 50, the term "pharmaceutical composition" implies a therapeutic use and it is noted that the specification fails to provide any guidance for using the claimed nucleic acid for any type of therapy. As such, a skilled artisan would recognize that further experimentation is required to determine whether SEQ ID NO:11 can be used for as a therapeutic compound.

Claim Rejections - 35 USC § 112, Second Paragraph

[9] The rejection of claim 48 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "mature form of the polypeptide of SEQ ID NO:12" is maintained for the reasons of record as set forth at item [14], part [b] of the Office action mailed April 29, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the specification states the meaning of the term "mature," citing pp. 38 and 93. Applicants' argument is not found persuasive.

Even in view of applicants' cited "definition" of the term "mature," it is unclear to the examiner as to what portion of the polypeptide of SEQ ID NO:12 applicants consider to be the "mature" form of the polypeptide. Based on the text cited by applicants in the response, it appears that the intended "mature" form of SEQ ID NO:12 *may* be amino

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acids 20 to 536 of SEQ ID NO:12. However, this is not expressly stated and it remains unclear as to whether this is the intended "mature" form. As such, it is unclear as to the scope of claimed polynucleotides. Clarification is requested.

[10] In a previous Office action, claim 49 was rejected as being confusing in the recitation of "nucleic acid sequence encoding the complement." See item [14], part [c] of the Office action mailed April 29, 2004. In view of applicants' clarification of the term "complement," the rejection is withdrawn. In order to clarify the record, it is noted that applicants have clarified the meaning of the term "complement" as a full-length complement, and not a fragment or partial complement.

Claim Rejections – Double Patenting

[11] The provisional obviousness-type double patenting rejection of claim 48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of US non-provisional application 10/453,372 is maintained for the reasons of record as set forth at item [15] of the Office action mailed April 29, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue that because the claims have not been patented, no action is required at this time. As applicant has taken no action to overcome the rejection, the rejection is maintained.

Conclusion

[12] Status of the claims:


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- Claims 42-51 are pending.
- Claims 42-51 are rejected.
- No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


David J. Steadman, Ph.D.
Primary Examiner
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